REMARKS

It is respectfully requested that this application be reconsidered in view of the following remarks and that all of the claims currently under examination be allowed.

Claim Amendments

Claims 9 and 17-23 are canceled without prejudice.

Claim 1 is amended to include that the amount of polymer in the composition is from about 2 to about 40 weight percent based on the total weight of the composition. Support for this amendment may be found, for example, in originally presented claim 9.

Claim 10 is amended to correct its dependency from canceled claim 9 to claim 1.

Applicants specifically reserve the right to file one or more continuing applications directed to the canceled subject matter.

No new matter has been added by this amendment. Applicants request entry of this amendment.

Claim Status

Claims 1-8 and 10-16 are pending.

Claims 9, 17-23 are canceled.

Interview Summary

The undersigned would like to thank Examiner Samala for the courtesy extended to herself and Dr. Hugo Eng during the interview of October 16, 2007. The Interview Summary provided by Examiner Samala accurately reflects the discussion held.

Applicants acknowledge that the Examiner expressed concerned regarding the possible indefiniteness of the phrase "greater than about 0.055" used in referring the ratio of

biocompatible polymer to contrast agent as there is no upper limit of the recitation recited. Applicants have amended the claims to include the amount of polymer in claim 1. As currently presented, claim 1 includes the amount of polymer, the amount of contrast agent in the composition, and the lower threshold for the ratio and therefore, the upper threshold of the ratio can be inferred from the variables provided.

Correction of Inventorship under 37 C.F.R. §1.48(a)

It has recently come to the attention of the Applicants that through error and without deceptive intent, the inventorship was improperly set forth, and accordingly, this application is corrected in compliance with 37 C.F.R. §1.48(a). The appropriate forms to correct inventorship are included herewith. Specifically, inventorship of this application has been changed by the addition of Brian Strauss and Brian Canfield.

Declaration Under 37 C.F.R. §1.132

The Examiner expressed an interest in Applicants filing an inventor declaration providing additional visualization data. See, Interview Summary, mailed on October 23, 2007. In response, Applicants submit herewith a Declaration of Brian M. Strauss under 37 C.F.R. §1.132. As stated above, Applicants are also petitioning to have Mr. Strauss added as an inventor.

Rejections Under 35 U.S.C. § 102(b)

Claims 1-3 and 5-16 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Evans, et al., U.S. Patent No. 6,342,202 ('202 patent) and Greff, et al., U.S. Patent No. 5,667,767 ('767 patent). For the following reasons, this rejection is traversed.

Initially, it is well established law that in order for a reference to anticipate a claim, the reference must disclose all of the claim elements either explicitly or inherently. Applicants continue to submit that the prior art references do not teach an embolic composition as currently claimed.

Applicants' Claimed Invention

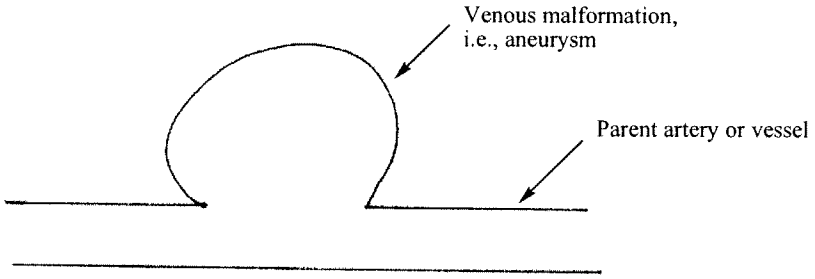
The claimed invention is directed to a composition comprising:

1. A biocompatible polymer;
2. A biocompatible solvent; and
3. **from greater than about 40 to about 60 weight percent** of a water-insoluble, biocompatible contrast agent;

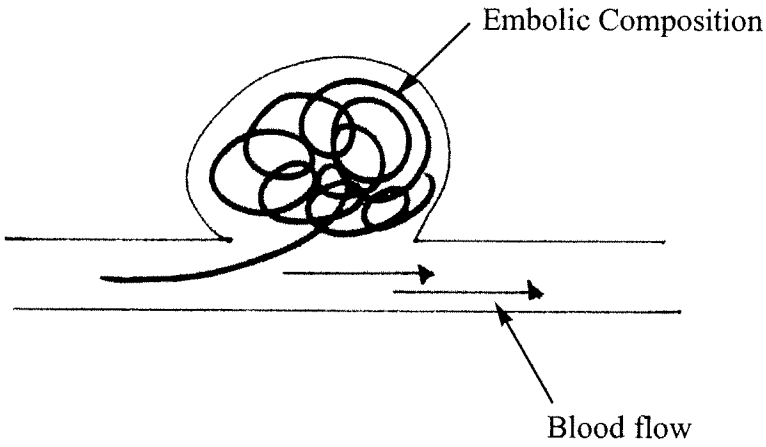
wherein the ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent **is about 0.055 or greater.**

Thus any reference must teach **both** the high amount of contrast agent, i.e., greater than about 40%, **and** the ratio of polymer to contrast agent.

The compositions of the invention are useful in embolizing blood vessels, i.e. aneurysms. Provided below is a schematic of a vasculature malformation, such as an aneurysm, which could benefit from compositions of the invention.



The biocompatible polymer is soluble in the solvent but is immiscible in blood. Therefore, when the polymer is delivered to the vascular site, the solvent dissipates leaving a solid polymer mass in the aneurysm. Because the aneurysm is filled with the polymer precipitate, normal blood flow may be resumed in the parent artery. This is best explained by the following diagram:



As outlined in the enclosed Declaration of Brian M. Strauss under 37 C.F.R. § 1.132 (hereinafter "Strauss Declaration"), it is desirous to maintain good visualization of the aneurysm fill to ensure an accurate and effective fill. "Inconsistent visibility can result in either the under-filling or over-filling of the vascular site to be embolized, thereby producing an unsatisfactory result." See, the specification, at page 3 [011]. Improved visualization is achieved by adding additional contrast agent thereby enhancing the radiopacity of the composition. See, Figure 1 of the specification, and Figure A of the Strauss Declaration.

Prior to this invention, addition of additional contrast agent led to a polymer precipitate that was not cohesive. It has now been found that by using a ratio of polymer to contrast agent of 0.055 or greater, a cohesive precipitate may result even when using higher amounts of contrast agent. By obtaining a cohesiveness precipitate, the undesired shedding of particles *in vivo* is avoided. See, the specification, page 5 [0018].

Evidence of the cohesiveness of the polymer precipitate formed from embolic compositions of the invention is found in Example 3 of the specification and the Strauss Declaration. As noted in Example 3, the cohesiveness of the precipitate is measured by determining the amount of particulate shedding. The precipitate is considered cohesive if there are no more than 25 particles per milliliter of test solution. Samples 10, 11, 13, 15 are included with the scope of the invention and were shown to be cohesive. Further, the additional

compositions discussed in the Strauss declaration, which are also within the scope of the invention, were found to be cohesive.

Evans et al. and Greff et al.

The Office Action states on page 2 that:

> ...both Evans et al. and Greff et al. clearly teaches the ratio[] of biocompatible polymer to the water-insoluble contrast agents used in the compositions suitable for use in embolizing blood vessels. Evan[s] teaches [a] composition comprising 5.8 weight percent poly(carbonate-urethane), ***20*** weight percent tantalum in DMSO...This ratio reads on the limitations of the instant claims. (emphasis added)

Evans et al. may teach compositions which have the claimed ratio; however, Evans et al. does not teach the amount of contrast agent, i.e. greater than about 40%, in combination with the ratio. For example, the Office has cited to a composition taught by Evans wherein the composition only contains 20% contrast agent. In light of the fact that Evans et al. does not teach every claim limitation of the instant invention, the claimed invention is novel.

The Office Action further states on page 2-3 that:

> ...Greff teaches composition[s] comprising 6 weight percent of the ethylene vinyl alcohol copolymer, ***35*** weight percent of a tantalum contrast agent in DMSO (again this proportion will give a ratio[] of 0.171...

Applicants would again like to point out that Greff et al. may teach the ratio but Greff et al. does not teach the claimed amount of contrast agent, i.e., greater than about 40%, **in combination with** the polymer to contrast agent ratio. Again, the Office has pointed to an example of a composition wherein the amount of contrast agent is lower than the claimed amount.

The Office Action still further states on page 3 that:

> Further, any prior art that is capable of performing said function in the instant invention (the prior art need not recite the same function, but only

> the same means) is encompassed by said means. For example, embolization techniques requiring deep vascular penetration will require a composition having specifically, suitable polymers ideally be soluble in the biocompatible solvent, be easy to deliver via a catheter or a syringe, be compatible with a contrast agent, and the resulting precipitate should form a well defined coherent mass to successful embolization.

Applicants submit, as evidenced the Strauss Declaration, that the prior art composition is not capable of performing the same function as the composition of the instant application. Particularly, the compositions of the art did not contain greater than about 40 weight percent of contrast agent and therefore are not as radiopaque as the compositions of the invention. As such, the composition of the instant application is not anticipated by the references cited.

Withdrawal of this rejection is respectfully requested.

Conclusion

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-041. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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